IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| GENENTECH, INC. and CITY OF HOPE, | ) | |
| | ) | |
| *Plaintiffs*, | ) | |
| | ) | |
| v. | ) | Civ. No. 17-1407-GMS |
| | ) | Civ. No. 17-1471-GMS |
| AMGEN INC. | ) | |
| | ) | |
| *Defendant*, | ) | |

**MEMORANDUM**

In two related patent-infringement actions, plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech") have asserted multiple counts against defendant Amgen Inc. ("Amgen") based on Amgen's plans to commercialize Mvasi™, a biosimilar version of Genentech's Avastin®. During the parties' so-called patent dance, Amgen made a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) that it did not intend to begin commercial marketing of Mvasi™ before December 18, 2018. Amgen later served notice that it would not commence commercial marketing before April 4, 2018, a date earlier than the one previously provided. Accordingly, Genentech seeks a declaratory judgment in both actions that Amgen cannot market Mvasi™ before December 18, 2018. (*See* Civ. No. 17-1407, D.I. 41 at ¶¶ 36-42 (count I); Civ. No. 17-1471, D.I. 39 at ¶¶ 336-46 (count 30)).[1] Amgen has moved to dismiss these counts—which the court will refer to as the "commercial marketing" claim—for failure to state a claim and for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(6) and 12(b)(1) respectively. (Civ. No. 17-1407 at D.I. 45; Civ. No. 17-1471 at D.I. 43). For the reasons stated below, the court finds

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[1] Because the parties make essentially identical arguments in both actions, all cites hereinafter are to the docket for Civ. No. 17-1407 unless stated otherwise.

that it currently lacks subject matter jurisdiction over Genentech's commercial marketing claim. Accordingly, Amgen's motion is granted, and Genentech's commercial marketing claim is dismissed without prejudice.

## I. BACKGROUND

On January 4, 2017, the FDA accepted Amgen's Abbreviated Biologics License Application ("aBLA") for Mvasi™, thereby kicking off the "patent dance" prescribed by the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262(*l*). (D.I. 41 ¶¶ 2, 5). The patent dance is a carefully calibrated statutory scheme that requires the "reference product sponsor" (i.e., Genentech) and the "applicant" (i.e., Amgen) to disclose and exchange information in furtherance of "preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664, 1670 (2017).

Pursuant to paragraph (3)(A) of the patent dance, Genentech provided Amgen with a list of 27 patents over which "a claim of patent infringement could reasonably be asserted." (D.I. 41 ¶ 8 (citing 42 U.S.C. § 262(*l*)(3)(A)). At that point, Amgen had to make a choice under paragraph (3)(B): argue that the patents are "invalid, unenforceable, or will not be infringed by the commercial marketing of [Mvasi™]," or make a "statement that [it] does not intend to begin commercial marketing of [Mvasi™] before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B).

On May 23, 2017, Amgen served its response. (D.I. 41 ¶ 9). It challenged 19 of the 27 patents as "invalid, unenforceable, or not infringed" and declared that it does not intend to begin commercial marketing of Mvasi™ before December 18, 2018, when all of the 8 remaining patents will have expired. (*Id.*). Then, on October 6, 2017, Amgen provided notice under paragraph (8)(A) that it "will commence commercial marketing of Mvasi™ … no earlier than 180 days from

the date of this letter." (D.I. 41 at ¶ 17; D.I. 47-1, Ex. A). In other words, Amgen provided notice that it would not commence commercial marketing before April 4, 2018, which is 8 months earlier than the December 18, 2018 date previously provided. Genentech's commercial marketing claim seeks to enforce Amgen's earlier representation that it would not launch Mvasi™ until the later December date.[2] (D.I. 1).

## II. STANDARD OF REVIEW

The party asserting subject matter jurisdiction has the burden of proving its existence. *Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). "Challenges to subject matter jurisdiction under Rule 12(b)(1) may be facial or factual." *Id.* (quoting *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249, 257 (3d Cir. 2009)). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *Id.* In reviewing a facial attack, the court considers only the allegations in the complaint and any documents referenced in or attached to the complaint, in the light most favorable to the plaintiff. *Church of Universal Bhd. v. Farmington Twp. Supervisors*, 296 F. App'x 285, 288 (3d Cir. 2008). In contrast, when reviewing a factual attack, the court may weigh and consider evidence outside the pleadings. *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). Finally, in a factual challenge, "no presumptive truthfulness attaches to plaintiffs' allegations." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

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[2] As part of briefing on the motion to dismiss, Genentech provided several letters the parties exchanged regarding Amgen's commercial marketing notice. (*See* D.I. 54, Exs. 1-7). On a motion to dismiss, the court is confined to the allegations in the complaint, exhibits attached to the complaint, documents incorporated by reference, and items subject to judicial notice. *Szczuka v. Delaware*, 2018 WL 934599, at *2 (D. Del. Feb. 16, 2018). These letters were not referenced in the complaint nor attached to the complaint. Thus, there is no basis for the court to consider them without converting this motion to dismiss into a motion for summary judgment.

## III. DISCUSSION

Amgen argues that there is no cognizable legal theory that would grant Genentech the relief it seeks from the commercial marketing claim. (D.I. 46 at 12-13, D.I. 53 at 4-11). In the alternative, Amgen argues that if Genentech is relying on a quasi-contract theory, there is no binding representation, no breach of a binding of representation, and no detrimental reliance. (D.I. 46 at 13-16). Genentech responds that its commercial marketing claim is not based on a quasi-contract theory. (D.I. 53 at 10-11). Instead, the claim is based on a private right action arising under the BPCIA itself. (*Id.*). This is a novel legal theory not yet addressed by any court. More important, there is no need to delve into this unchartered territory at this time.

For a court to exercise jurisdiction under the Declaratory Judgment Act, there must be an "actual controversy." 28 U.S.C. § 2201(a). The controversy must be "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 2017 WL 2559735, at *1 (D. Del. June 13, 2017) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). It is unclear whether Amgen will actually launch Mvasi™ before December 18, 2018. Genentech points to no evidence of an actual controversy other than the notice of commercial marketing. The 180 days in the commercial marketing notice expired on April 4, 2018, and there is no indication that Mvasi™ has actually launched. The court recently heard from the parties at a scheduling conference. The parties are currently engaged in discovery and appear interested in cooperating. The court is left with the impression that the commercial marketing claim is not of "sufficient immediacy" to warrant the issuance of a novel declaratory judgment. If this claim ripens into an actual controversy, where Amgen launches Mvasi™ before December 18, 2018, there will be an opportunity for Genentech to seek a temporary restraining order or a preliminary injunction at that time.

## IV. CONCLUSION

For the foregoing reasons, Amgen's motions to dismiss (Civ. No. 17-1407 at D.I. 45; Civ. No. 17-1471 at D.I. 43) are granted. Count 1 of the 17-1407 complaint and count 30 of the 17-1471 complaint are dismissed without prejudice. An appropriate order will be entered.

Dated: April 17, 2018

UNITED STATES DISTRICT JUDGE